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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,623	11/17/2000	Steven Pelech	033099-003	7809

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,623

Applicant(s)

Pelech

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/14/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above, claim(s) 1-22 and 30-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 04/07/2003 is acknowledged. Applicant elected, with traverse, Group I.3, claims 1-7 (generic claims), 23-29. Applicant argues that a combined search of groups I-IV will not impose an undue burden. Examiner disagrees. As was stated in the restriction requirement, methods of Group I can be practiced by another materially different apparatus, such as a calculator, or by hand; further, computer medium and computer signal of Groups III, IV are separate and patentably distinct from the methods of Group I because the method can be executed without a computer, and because a computer readable medium or a computer signal can contain any type of information, other than the instantly specified in claims 69,70. Consequently, a reference teaching one group would not necessarily teach another. The restriction requirement is still deemed proper and is therefore made FINAL. In regard to claims 1-7, Examiner withdraws from position that they are linking claims because claim 23 is not drawn to coregulation of "comparison value" which reflects, as in claim 1, physical properties of proteins (see rejection under 35 U.S.C. 112, second paragraph, below). Claims 1-22, 30-70 are withdrawn from further consideration by the examiner, 37

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CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 8-22, 30-70 and amending claims 1-7 to read on the elected group is requested.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 23 (and claims dependent thereupon) lack antecedent basis: Claim 23 is dependent on claim 1 and specifies determination of "comparison value". However, while claim 1 address "comparison value" as "representing physical properties" of

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proteins, claim 23 defines the "comparison value" as a function of expression and functional properties, which are not "physical properties".

B. Claims 25, 26, 27: the claims recite "threshold linkage value". The metes and bounds of this parameter, which is critical for the execution of the claimed method, are not defined and the term is vague and unclear. The specification, although providing particular examples, does not provide a standard for ascertaining the requisite "threshold value", and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-29 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Detection of proteins by electrophoresis and Western blot is described in specification (e.g. pages 13 through 25) as critical or essential to the practice of the invention, but not included in the claims and the

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method without these steps is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

5. Claims 23-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying association between kinases, does not reasonably provide enablement for identifying association between any other cell signaling proteins. The specification provides examples on determining coregulation coefficient based on phosphorylation. Neither other parameters used for determining regulation or co-regulation of proteins, nor guidance on what constitutes coregulation, how to determine it, and how to define the threshold value used for comparing, are defined in the disclosure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

6. Further, claims 23-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying association between proteins using linkage coefficient obtained by division of coregulation coefficient by coexpression coefficient (i.e., as in claim 24), does not reasonably provide enablement for using linkage coefficient obtained by other mathematical operations. There is no

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disclosure of any other functions linking coregulation and coexpression coefficients to association between proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Conclusion.

7. No claims are allowed
8. Claims 23-29, if limited to method of determining association of kinases using linkage coefficient as defined in claim 24, and if rewritten to overcome the rejections under 35 U.S.C. § 112, first and second paragraphs, and to include all of the limitations of the base claim and any intervening claims would be allowable over the prior art of record or any combination thereof.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 30, 2003

mlb